
Amendments to the MTCA Cleanup Regulation

December 11, 2006

Prepared by

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Toxics Cleanup Program

Rulemaking Issues for SAB Review

- Common Mechanism of Action/Mode of Action
 - Dioxin/Furans
 - Dioxin-Like PCBs
 - PAHs
 - Other Hazardous Substances
- Dioxins/Furans - Use of 2005 WHO TEF Values
- Dioxin-Like PCBs - Use of 2005 WHO TEF Values
- PAHs - Use of Cal EPA 2005 PEF Values
- TEFs for Other Hazardous Substances
- Dioxins/Furans - Default GI Absorption Fraction
- Dioxins/Furans - Default Dermal Absorption Fraction
- Application of TEFs/PEFs to Abiotic Media
- Cross-Media Transfer

Dioxins/Furans - GI Absorption

- Ecology is considering establishing a default gastrointestinal absorption factor for dioxin/furan mixtures equal to 0.4. Is this default value consistent with current scientific information?
- Ecology rationale:
 - ❑ Approach has a strong underlying scientific basis (soil matrix effect) that is consistent with several expert committee findings
 - ❑ Revised default value falls within the range of experimental results
 - ❑ Revised default value is consistent with EPA Dioxin Reassessment
 - ❑ Use of default value produces exposure estimates that fall near the 95th percentile of simulated exposure distributions

Relative Bioavailability

$$\text{Gastrointestinal absorption fraction (AB1)} = \frac{\text{ABS}_{\text{(Soil Study)}}}{\text{ABS}_{\text{(Tox Study)}}}$$

Where:

ABS (Soil Study) = % of soil-bound contaminant absorbed following ingestion of soil particles

ABS (Tox Study) = % of contaminant absorbed following ingestion in the toxicological study used to establish cancer slope factor or reference dose

Board's Response and Questions

- The Board reached several conclusions at the October 23rd meeting:
 - ❑ Reasonable to conclude that soil-bound dioxins and furans are less bioavailable than dioxins and furans in foods and drinking water.
 - ❑ Need to consider the absorption of dioxins and furans in soils relative to the amount of absorption in the toxicological studies that were used to establish the cancer slope factors and reference doses.
 - ❑ Reasonable to assume that test animals absorbed 80% of the administered dose in the toxicological study used to establish the cancer slope factor for dioxins and furans (Kociba et al. 1978)
- The Board did not reach a conclusion on the use of a 30% absorption value for soil-bound dioxins and furans.
- The Board requested that Ecology provide additional information on:
 - ❑ Designs of key studies (e.g. soil types, test methods, etc.);
 - ❑ Range of soil types at Washington cleanup sites
 - ❑ Range of factors that might influence inter- or intra-individual variability in absorption rates.

Summary of Bioavailability Studies

- Six studies evaluated oral absorption of soil-bound TCDD from soil collected at 5 sites. Experimental protocols, animal species, and measured endpoints varied among the studies.
 - ❑ Data from the studies suggest that bioavailability could range from $< 1\%$ to approximately 100%.
 - ❑ Absorption of soil-bound TCDD may be influenced by soil type (% carbon content), duration of contact with the soil, and different soil characteristics.
 - ❑ Absorption and distribution of soil-bound TCDD appears to be dose-specific and species-specific.
 - ❑ Calculated bioavailability varied depending on how absorption efficiencies were measured, (i.e., liver tissue concentrations, enzyme induction, blood serum levels, etc),
- Little published information for other congeners in soil. Studies of dioxins/furans administered orally in other media (e.g., food or oil) suggest that absorption may also be congener-specific.

Bioavailability Studies

Table 1: Summary of Dioxin Bioavailability Studies

End Point	All Studies	Liver Content	AHH Induction	P450 Induction
# of Studies	39	19	12	8
Range	0.25-121	0.25-71	49-121	65-117
Average	66	46	84	87
Median	65	52	87	87

Soil Types in Washington

- Several factors influence the bioavailability of soil-bound dioxins.
- Soil types used in the animal bioavailability studies are not well characterized.
- Wide range of soil types present in Washington. It is difficult to compare soils in animal studies with Washington soils.

Quality of Information Criteria

- Theory and technique with widespread acceptance in relevant scientific community;
- Standard testing methods or widely accepted scientific methods;
- Review of relevant information (support and non-support) and rationale for proposed modification;
- Valid assumptions that err on side of protecting human health and the environment;
- Highly-exposed populations;
- Quality assurance/quality control, limitations of information, etc.

Theory and Technique

- Ecology believes that the theory and/or assumption underlying the proposed revisions (soil matrix effect) has widespread acceptance in relevant scientific community.
 - ❑ National Academy of Sciences (2003)
 - ❑ National Research Council (2003)
 - ❑ EPA Dioxin Reassessment (EPA, 2004)
 - ❑ Van den Berg et al. (2006)
 - ❑ MTCA Science Advisory Board (October 2006)

Standard Testing/Scientific Methods

- Standard testing methods or widely accepted scientific methods
 - ❑ The peer reviewed studies that Ecology has evaluated appear to use reasonable scientific principles and methods to evaluate soil bioavailability.
 - ❑ There are currently no standard testing methods or a single testing method that has widespread use or acceptance within the scientific community.
 - ❑ The National Research Council (NRC, 2003) stated that the tool box of methods for understanding the bioavailability processes in soils is incomplete.

Review of Relevant Information

Support

- Sound conceptual basis
- Revised default range falls within range of study results
- Consistent with EPA Dioxin Reassessment
- Results in protective exposure estimates

Not Support

- Fails to account for intra- & intra-individual variability
- Fails to account for variability in soil characteristics
- Wide range of study results
- Relevance/interpretation of study results

Protection of Human Health

■ Assumptions

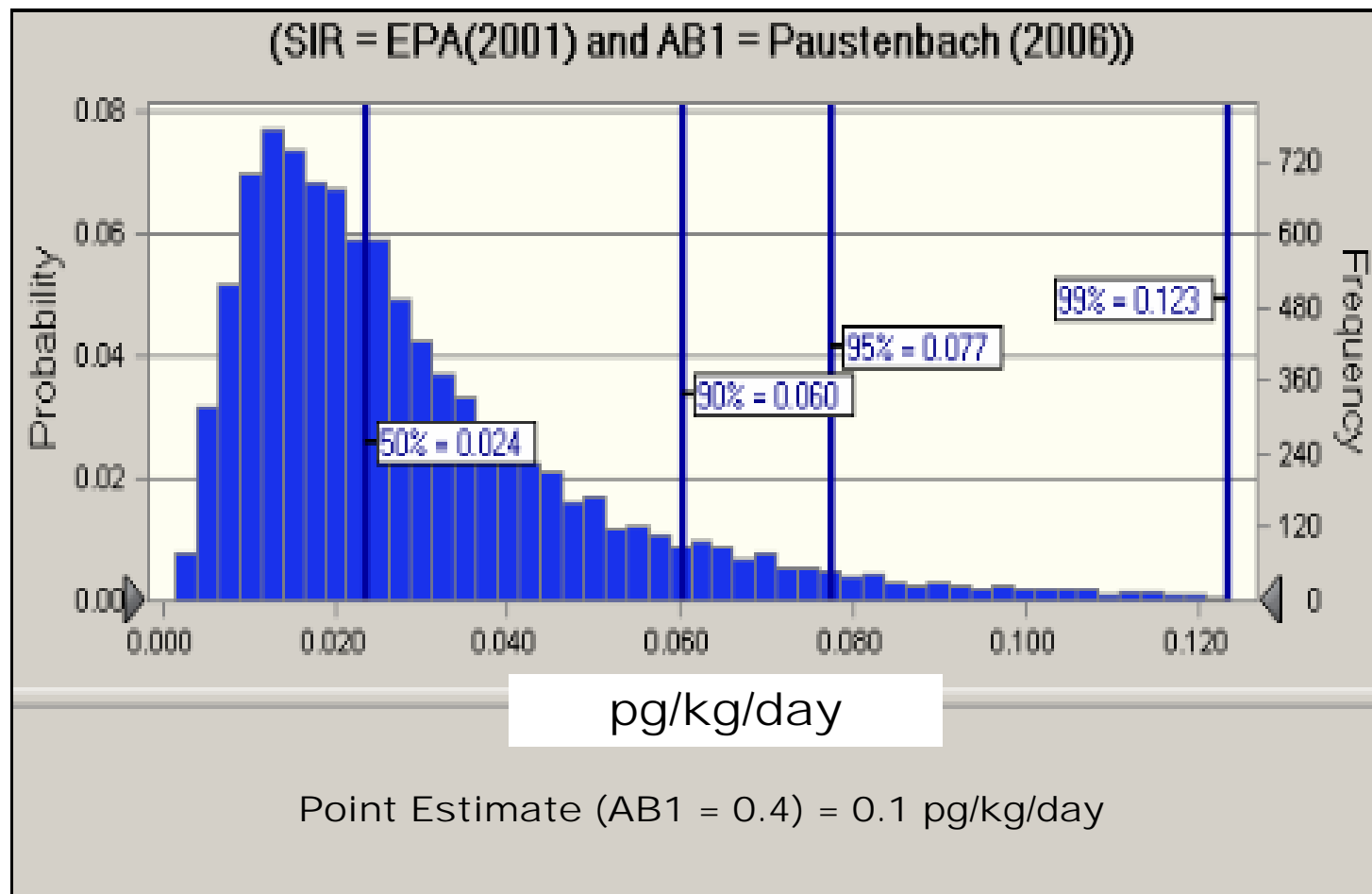
- ❑ Soil matrix effect
- ❑ Use of animal study results to predict human health risks
- ❑ Bioavailability of TCDD vs higher chlorinated congeners
- ❑ Relationship between soils in animal studies & Washington soils

■ Protection of Human Health and the Environment

- ❑ MTCA cleanup levels based on reasonable maximum exposure
- ❑ Computer simulation techniques provide a tool for evaluating how the variability in individual exposure parameters contribute to variability in exposure estimates
- ❑ Point estimates fall at upper end of simulated exposure distributions

Supplementary Materials

Average Daily Dose (pg/kg/day)



Highly-Exposed Populations

- Children have the highest potential for exposure to contaminated soils.
- MTCA soil cleanup levels are based on reasonable maximum exposure
 - ❑ Child exposure patterns
 - ❑ Variability in exposure patterns (e.g. SIR)
- Factors that might increase absorption:
 - ❑ Diets high in fatty foods
 - ❑ Genetic traits?
 - ❑ Disease?

Quality Assurance

- Quality assurance/quality control, limitations of information, etc.
 - ❑ Ecology relied on peer-reviewed scientific studies and expert committee evaluations.
 - ❑ Studies have used generally accepted protocols (no standard methodology)
 - ❑ There are several limitations with available studies:
 - Limited number of studies
 - Limited information on soil types/study design
 - Limited soil types
 - Large variability in study results.

Dioxins/Furans - GI Absorption

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Next Steps

- Review Science Advisory Board Comments/Advice
- Internal Ecology Discussions on Rule Scope and Schedule
- Complete Cost/Benefit Analysis etc.
- Complete Proposed Rule Page (CR 102)
 - Proposed rule language
 - Regulatory analyses
 - SEPA Checklist
- Formal Public Review with Hearings in early 2007 (pending completion of supporting analyses).
- Prepare Final Rule Adoption Package – Spring 2007

For Further Information

Department of Ecology
Toxics Cleanup Program
Rule web site:

http://aww.ecydev/programs/tcp/regs/amendment_2006/amend.htm

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